



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2012-0061; FRL-9337-7]

Petition to Demonstrate Paperwork Reduction Act Compliance of the Endocrine Disruptor Screening Program; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is seeking public comment on a December 7, 2011 petition from the Chemical Producers & Distributors Association (CPDA), the Halogenated Solvents Industry Alliance, Inc., and the People for the Ethical Treatment of Animals (PETA). The petition requested that the Agency abide by the Paperwork Reduction Act and Office of Management and Budget Terms of Clearance for the approved Information Collection Request (ICR) of the first list of 67 chemicals to receive orders under the Endocrine Disruptor Screening Program by demonstrating the information being sought has practical utility and is not duplicative before proceeding with Tier 1 screening orders for additional chemicals.

DATES: Comments must be received on or before [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2012-0061, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P),

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2012-0061. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may

not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Jane Smith, Pesticide Re-Evaluation Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0048; fax number: (703) 308-8005; email address: smith.jane-scott@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders, including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides and other chemical substances; or if you are or

may otherwise be involved in the testing of chemical substances for potential endocrine effects. Potentially affected entities identified by the North American Industrial Classification System (NAICS) codes, may include, but are not limited to:

- Chemical manufacturers, importers and processors (NAICS code 325), e.g., persons who manufacture, import or process chemical substances.
- Pesticide, fertilizer, and other agricultural chemical manufacturing (NAICS code 3253), e.g., persons who manufacture, import or process pesticide, fertilizer and agricultural chemicals.
- Scientific research and development services (NAICS code 5417), e.g., persons who conduct testing of chemical substances for endocrine effects.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA). If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the

outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:
 - i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
 - ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
 - iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
 - iv. Describe any assumptions and provide any technical information and/or data that you used.
 - v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
 - vi. Provide specific examples to illustrate your concerns and suggest alternatives.
 - vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
 - viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

In October 2009, the Agency initiated the Endocrine Disruptor Screening Program (EDSP) Tier 1 screening for the first list of 67 chemicals by issuing orders between October 29, 2009, and February 26, 2010, pursuant to the authority provided to EPA under section 408(p)(5) of FFDCA. The orders require the testing of chemicals through 11 Tier 1 screening assays. The purpose of the 11 Tier 1 screening assays is to determine the potential for a chemical to interact with estrogen, androgen and thyroid hormone systems. Based on the data from the 11 Tier 1 assays, should the determination be made that the chemical is shown to interact, additional Tier 2 testing may be required.

EPA is seeking public comment on a December 6, 2011 petition from the Chemical Producers & Distributors Association (CPDA), the Halogenated Solvents Industry Alliance, Inc., and the People for the Ethical Treatment of Animals (PETA). The petition requested that the Agency abide by the Paperwork Reduction Act and Office of Management and Budget Terms of Clearance for the approved Information Collection Request (ICR) of the first list of 67 chemicals to receive orders under the Endocrine Disruptor Screening Program by demonstrating that the information collected: (1) Has practical utility in that it can distinguish whether a chemical has the potential to interact with the endocrine system or not; (2) has practical utility before proceeding with more Tier 1 screening orders for additional chemicals; and (3) is not duplicative of other information collection activities by the Agency but also is not duplicative of existing information.

B. What is the Agency's Authority for Taking this Action?

This action is taken under the authority of FFDCA section 408(p), 21 U.S.C. 346a(d)(3).

List of Subjects

Environmental protection, EDSP, Endocrine Disruptors Screening Program,
FFDCA orders, List 1 chemicals, Pesticides.

Dated: February 15, 2012.

Michael Goodis,

Acting Director, Pesticides Re-Evaluation Division,
Office of Pesticide Programs.

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